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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/534,376

Applicant(s)

ALITALO ET AL.

Examiner

Eileen B. O'Hara

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1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - A. Claims 1-37, in so far as they are drawn to a method of regulating endothelial cell growth or treating a patient by administration of a VEGF-C polypeptide, classified in class 514, subclass 2, for example.
 - B. Claims 5 and 8, in so far as they are drawn to a method of treating a patient by administration of an antibody to a VEGF-C polypeptide, classified in class 514, subclass 2, for example.
 - C. Claims 38 and 39, drawn to a method for screening for inhibitors of the Flt4 receptor kinase by binding assay, classified in class 435, subclass 7.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions A and B are related in that they both are methods of treatment, but the methods are distinct because they use distinct products, which require non-coextensive searches.

Inventions A and C are related in that they both use a common product, the VEGF-C polypeptide. In the instant case the VEGF-C polypeptide can be used in the method of treatment of invention A, and also as the ligand in the screening assay for inhibitors of Flt4 tyrosine kinase, but these are materially different methods because they require different starting materials (except for the polypeptide), methods steps and goals.

Inventions B and C are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of treatment with anti-VEGF-C antibody has different starting materials, steps and goals from the method of screening for inhibitors of Flt4 tyrosine kinase.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. If invention A is elected, restriction to one of the following inventions is also required under 35 U.S.C. 121:

- I. VEGF-C having the amino acid sequence of SEQ ID NO: 8.
- II. VEGF-CA156, wherein the cysteine residue at position 156 of SEQ ID NO: 8 has been deleted or replaced by another amino acid.
- III. VEGF-CA152, wherein the cysteine residue at position 156 of SEQ ID NO: 11 has been deleted or replaced by another amino acid.
- IV. VEGF-CA155, wherein the cysteine residue at position 156 of SEQ ID NO: 13 has been deleted or replaced by another amino acid.

Species Election

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2. If Group A is selected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

II. Method of using VEGF-C having the amino acid sequence of SEQ ID NO: 8.

I. Method of using VEGF-C Δ 156, wherein the cysteine residue at position 156 of SEQ ID NO: 8 has been deleted or replaced by another amino acid.

III. Method of using VEGF-C Δ 152, wherein the cysteine residue at position 156 of SEQ ID NO: 11 has been deleted or replaced by another amino acid.

IV. Method of using VEGF-C Δ 155, wherein the cysteine residue at position 156 of SEQ ID NO: 13 has been deleted or replaced by another amino acid.

V. Method of using a polypeptide lacking at least carboxy-terminal residues of SEQ ID NO: 8 beyond residue 227,

VI. Method of using a polypeptide including from residue 161-211 and lacking at least carboxy-terminal residues of SEQ ID NO: 8 beyond residue 227,

VII. Method of using a polypeptide including from residue 131-211 and lacking at least carboxy-terminal residues of SEQ ID NO: 8 beyond residue 227,

VIII. Method of using a polypeptide including from residue 113-213 and lacking at least carboxy-terminal residues of SEQ ID NO: 8 beyond residue 227,

IX. Method of using a polypeptide including from residue 32-227 and lacking at least carboxy-terminal residues of SEQ ID NO: 8 beyond residue 227.

Group II, selection from one of the following variants of VEGF-C Δ 156, wherein the

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cysteine residue at position 156 of SEQ ID NO: 8 has been deleted or replaced by another amino acid:

X. Method of using a variant of VEGF-CA156, wherein the cysteine residue at position 156 of SEQ ID NO: 8 has been deleted or replaced by another amino acid.

XI. Method of using a variant of VEGF-CA156, wherein the cysteine residue at position 156 of SEQ ID NO: 8 has been deleted or replaced by another amino acid and having a continuous portion having as its amino acid terminal residue an amino acid between residues 102 and 114 of SEQ ID NO: 8 and having as its carboxy terminal residue an amino acid between residues 212 and 228 of SEQ ID NO: 8, or

XII. Method of using a variant of VEGF-CA156, wherein the cysteine residue at position 156 of SEQ ID NO: 8 has been deleted or replaced by another amino acid and having said polypeptide with an amino acid sequence set forth in SEQ ID NO: 8 from residue 103 to residue 227.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR
PRIMARY EXAMINER